UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF TEXAS
HOUSTON DIVISION

GIOVANNA BULOX, *et al.*, *Plaintiffs,*	§	
v.	§	Case No. 4:21-CV-02320
COOPERSURGICAL, INC., *et al.*, *Defendants.*	§	

ORDER ON PLAINTIFFS' *DAUBERT* MOTION FOR DR. SILVERMAN[1]

Before the Court is Plaintiffs' motion to exclude certain opinions of Defendants' expert witness, Steven David Silverman, an attorney who worked for the Food and Drug Administration ("FDA") from 2002 until 2015. ECF No. 130.[2] Plaintiffs argue that Silverman is not qualified to testify regarding Defendants' compliance with the FDA regulations, and his opinions are otherwise unreliable and unhelpful. ECF No. 130. Defendants respond that his two decades of medical device regulatory experience qualify Silverman to testify as an FDA medical device regulatory expert, and his opinions are reliable, relevant, and useful to the jury because they rebut Plaintiffs' FDA experts' opinions about Defendants' alleged non-compliance. ECF No. 145. Based on the briefing,[3] applicable law, and record,

[1] The district judge to whom this case is assigned referred this motion in accordance with 28 U.S.C. § 636(b). Order, ECF No. 173.

[2] The Court noted that one unresolved issue impacting the viability of Plaintiffs' claims is federal preemption: the primary defense Defendants raise in their pending motions for summary judgment, *see* ECF Nos. 123, 124, 125, and ordered counsel to identify which motions to strike experts are relevant to resolution of that question. ECF No. 174. Plaintiffs identified this as one of the relevant motions. ECF No. 176.

[3] Defendants filed a response, ECF No. 145, and Plaintiffs filed a reply, ECF No. 155.

Plaintiffs' motion is denied because the arguments raised are better suited for cross-examination at trial.

I. BACKGROUND

Defendants CooperSurgical, Inc., Femcare, Ltd., and Utah Medical Products, Inc. manufacture and distribute birth control devices called Filshie Clips. ECF No. 40 ¶ 19. Filshie Clips are 3-5 millimeters wide and are laparoscopically placed on the fallopian tubes. ECF No. 40 ¶ 21. Plaintiffs are individuals who had tubal ligation surgery in 2009 and 2010. ECF No. 40 ¶¶ 32, 46. In 2019, after years of experiencing pain, doctors removed two migrated Filshie Clips from Bulox's body, one in her intestinal wall. ECF No. 40 ¶¶ 36, 39, 42–45. Plaintiff Merlo also had pain several years after her surgery, and in 2020, radiology showed the Filshie Clips migrated in her body. ECF No. 40 ¶¶ 50–51. An attempt to remove them laparoscopically was unsuccessful. Merlo still has displaced Filshie Clips in her body. ECF No. 40 ¶¶ 52–53. Plaintiffs sued Defendants for: (1) design defect; (2) manufacturing defect; (3) failure to warn; (4) strict liability; (5) negligence; (6) violation of consumer protection laws; (7) gross negligence; and (8) exemplary damages. ECF No. 40 at 17–32.

Defendants designated Silverman as a rebuttal expert to Plaintiffs' expert, Joshua Sharlin, Ph.D., who opined that Defendants failed to meet the FDA's regulatory requirements. ECF No. 145 at 2. Defendants contend that Silverman "rebuts Dr. Sharlin's opinions by showing that they present untenable conclusions

and speculations about whether the FDA would find any non-compliance." ECF No. 145 at 2.

Arguing Silverman is unqualified and offers unhelpful and unreliable opinions, Plaintiffs seek to exclude several of Mr. Silverman's opinions, namely any opinion regarding: (1) CooperSurgical; (2) Femcare; (3) Utah Medical; (4) the adequacy of warnings promulgated with Filshie Clips; (5) whether any Defendant in this case provided regulators with clear and truthful information regarding Filshie Clips; (6) whether Filshie Clips, including the Instructions for Use, satisfy FDA regulatory requirements at times relevant to this lawsuit; and (7) whether Defendants in this case complied with FDA regulations regarding reporting adverse events and/or dealing with patient or provider reports or complaints. ECF No. 130 at 2.

II. RELEVANT LAW

Federal Rule of Evidence 702 provides that "[a] witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

District courts act as the gatekeeper in making determinations as to the admissibility of expert testimony. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993). As a preliminary matter, a district court must determine whether the proffered witness qualifies as an expert "by virtue of his knowledge, skill, experience, training, or education." *United States v. Cooks*, 589 F.3d 173, 179 (5th Cir. 2009) (quotation omitted). If the expert is qualified, the "overarching concern" becomes "whether the testimony is relevant and reliable." *Puga v. RCX Sols., Inc.*, 922 F.3d 285, 293 (5th Cir. 2019); *Bryant v. Intercontinental Terminals Co. LLC*, No. 4:19-CV-01460, 2023 WL 4108844, at *3 (S.D. Tex. June 21, 2023), *reconsideration denied*, No. 4:19-CV-01460, 2023 WL 4626676 (S.D. Tex. July 18, 2023) (quoting *Brown v. Illinois Cent. R. Co.*, 705 F.3d 531, 535 (5th Cir. 2013) (quoting *Daubert*, 509 U.S. at 589)). To be reliable, expert testimony must "be grounded in the methods and procedures of science and be more than unsupported speculation or subjective belief." *Johnson v. Arkema, Inc.*, 685 F.3d 452, 459 (5th Cir. 2012) (cleaned up). To be relevant, the expert's "reasoning or methodology [must] be properly applied to the facts in issue." *Id*. (quotation omitted).

"As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility." *Puga*, 922 F.3d at 294. A district court's role under Rule 702 "is not to weigh the expert testimony to the point of supplanting the jury's fact-finding role—the court's role is limited to ensuring that the evidence in dispute is at least sufficiently reliable

and relevant to the issue so that it is appropriate for the jury's consideration." *Id*. As the United States Supreme Court explained: "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596. "While the district court must act as a gatekeeper to exclude all irrelevant and unreliable expert testimony, 'the rejection of expert testimony is the exception rather than the rule.'" *Puga*, 922 F.3d at 294 (quoting Fed. R. Evid. 702 advisory committee's note to 2000 amendment).

The test of reliability is flexible—the Supreme Court has recognized the *Daubert* factors[4] "may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony." *First v. AGCO Corp.*, No. 7:21-CV-0006-O, 2022 WL 1199211, at *1

[4] To meet this gatekeeping function, the Court "must make 'a preliminary assessment of whether the reasoning or methodology underlying the testimony is . . . valid and of whether that reasoning or methodology properly can be applied to the facts in issue.'" *Bryant*, 2023 WL 4108844, at *3 (quoting *Brown*, 705 F.3d at 535) (quoting *Daubert*, 509 U.S. at 592–93). *Daubert* lists five non-exclusive factors to consider when assessing the validity or reliability of expert testimony:

1. Whether the theory or technique has been tested;
2. Whether the theory or technique has been subjected to peer review and publication;
3. The known or potential rate of error of the method used;
4. The existence and maintenance of standards and controls in the methodology; and
5. Whether the theory or method has been generally accepted by the scientific community.

Daubert, 509 U.S. at 593–95. These factors are not necessarily limited to scientific evidence and apply to testimony offered by non-scientific experts, depending upon "the particular circumstances of the particular case at issue." *Kumho Tire Company, Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999).

(N.D. Tex. Mar. 8, 2022) (quoting *Kumho Tire*, 526 U.S. at 150). A district court has wide latitude in deciding *how* to determine reliability, just as it has considerable discretion with respect to the ultimate reliability determination. *Id.* (emphasis added) (citing *Kumho Tire*, 526 U.S. at 152).

The offering party must prove "'by a preponderance of the evidence that the testimony is reliable,' not that it is correct." *Bryant*, 2023 WL 4108844, at *3 (quoting *Swanston v. City of Plano, Tex.*, 2021 WL 327588, at *2 (E.D. Tex. Feb. 1, 2021) (quoting *Moore v. Ashland Chem. Inc.*, 151 F.3d 269, 276 (5th Cir. 1998))). The trial judge's discretion "will not be disturbed on appeal unless manifestly erroneous." *Id.* (quoting *Watkins v. Telsmith, Inc.*, 121 F.3d 984, 988 (5th Cir. 1997) (cleaned up)).

III. SILVERMAN IS QUALIFIED TO TESTIFY AS AN FDA REGULATORY EXPERT.

Plaintiffs argue that Silverman is not qualified to testify because no court has qualified him as an expert, he lacks training in statistics, epidemiology, medicine, or causation, could not articulate the FDA's mission in his deposition, had no relationship with Defendants prior to this case, and lacks specialized knowledge about Filshie Clips. ECF No. 130 at 7. Defendants respond that Silverman's more than two decades of medical device regulatory experience qualify him to offer opinions in this case. ECF No. 145 at 2. Defendants point out that prior qualification from a court is not required under Rule 702. ECF No. 145 at 3–4. Defendants also note that although Plaintiffs challenge Silverman's qualifications in fields unrelated

to FDA regulatory compliance, none of his opinions stray into these challenged fields. ECF No. 145 at 3–4.

As an initial matter, Plaintiffs' cursory qualification argument lacks analysis and authority, aside from a basic overview of the law. For this reason alone, the Court rejects Plaintiffs' argument. *See Francisco E. v. Comm'r of Soc. Sec. Admin.*, No. 3:21-CV-3231-L-BK, 2023 WL 2450160, at *4 (N.D. Tex. Jan. 27, 2023), *adopted sub nom. Esparza v. Comm'r of Soc. Sec. Admin.*, No. 3:21-CV-3231-L-BK, 2023 WL 2160354 (N.D. Tex. Feb. 22, 2023) (where Plaintiff cites no case law, court found he has waived the issue) (citing *Nichols v. Enterasys Networks, Inc.*, 495 F.3d 185, 190 (5th Cir. 2007) ("Where analysis is so deficient, this court has considered the issue waived for inadequate briefing.")). *Accord* Judge Drew Tipton's Court Procedures, Rule 16(e) ("All motions or similar filings must contain . . . [a]n argument devoted to relevant, persuasive legal authority."); Judge Dena Palermo's Court Procedures, Rule IX.1 ("The Court requires concise, pertinent and well organized memoranda of law.").

Nonetheless, Silverman is highly qualified in the field of FDA regulatory compliance for medical devices. Silverman has worked in the medical device regulatory field since 2002, with over thirteen years working for the FDA in the areas of federal regulatory compliance review, enforcement of the Food, Drug, Cosmetic Act, and development of FDA enforcement policy. ECF No. 145-1 at 5–6, 17–18. Silverman served as Director for the FDA Office of Compliance at the

Center for Devices for five years. ECF No. 145-1 at 17. After his time at the FDA, Silverman worked for the past ten years as a medical device regulatory consultant. ECF No. 145-1 at 5–6, 16.

Plaintiff's approach for assessing Silverman's qualification to serve as an expert is far too granular for this case. *See Marathon Oil Co. v. Koch Energy Services, LLC*, No. 4:21-CV-1262, 2024 WL 1236487, at *2 (S.D. Tex. Feb. 5, 2024) (although the expert lacked experience as a trader, the court found that the expert's extensive knowledge of the oil and gas industry as a consultant and engineer sufficiently qualified him to testify as an expert in oil and gas supply and transportation strategies and contractual damages) (citing *Tendeka, Inc. v. Glover*, No. CIV.A. H-13-1764, 2015 WL 2212601, at *23 (S.D. Tex. May 11, 2015) (holding that although an expert "did not have experience in the specialized field of swellable-rubber compounding, his chemistry experience is more than sufficient to qualify him to opine on the chemical formulations at issue here.")); *see also Shrieve Chem. Products, Inc. v. Caremoli*, No. CV H-16-2173, 2018 WL 1558273, at *7 (S.D. Tex. Jan. 4, 2018) ("A lack of specialization should generally go to the weight of the evidence rather than its admissibility.") (quoting *United States v. Wen Chyu Liu*, 716 F.3d 159, 168 (5th Cir. 2013)). Here, Silverman has extensive experience in medical device compliance with the FDA, which is what Defendants have hired him to testify about. That his knowledge does not specifically involve Filshie Clips or Defendants or other unrelated areas of training does not render him unqualified—

these issues go to the weight, not admissibility of his testimony. *See Marathon Oil Co.*, 2024 WL 1236487, at *2.

Moreover, Plaintiffs' contention that Silverman is unqualified because a court has not previously found him qualified as an expert is unsupported by any authority. Rule 702 contains no such requirement. *See* Fed. R. Evid. 702; *see also Carrouche v. State Farm Fire & Cas. Co.*, No. CIV.A. 07-6532, 2008 WL 5561220, at *1 (E.D. La. June 26, 2008) (rejecting argument that expert was unqualified because he "has never offered any prior testimony in connection with a lawsuit, nor has he been qualified as an expert.").

Defendants have shown by a preponderance of the evidence that Silverman is qualified to testify as an expert in FDA compliance for medical devices.

IV. SILVERMAN'S OPINIONS ARE RELIABLE AND HELPFUL TO THE JURY.

Plaintiffs alternatively argue that Silverman's opinions are: (1) unhelpful because he does not opine about any of Defendants' alleged conduct in this case; and (2) unreliable because his opinion that he has seen no evidence of regulatory violation regarding Filshie Clips is based on a "curated, hand-picked sub-set of documents and complaints provided to him by [Defendants]," not "the full universe of migration complaints," which he failed to independently seek out. ECF No. 130 at 7–10. Defendants respond that Plaintiff's argument is misleading because Silverman's report contains opinions regarding Defendant's actions. ECF No. 145 at 7. Further, Defendants contend that Silverman reviewed the necessary materials

to rebut Plaintiffs' expert, Dr. Sharlin, *i.e.*, the documents Dr. Sharlin reviewed, and that this argument improperly shifts the burden to Defendants. ECF No. 145 at 7–8.

Addressing Plaintiffs' first argument, the Court finds that Silverman offers opinions related to Defendants' compliance with FDA requirements. ECF No. 45-1. In his report, Silverman opined that "Defendants certainly must satisfy FDCA requirements and they appear to have done so. This includes satisfaction of FDCA complaint handling, medical-device reporting, and device labeling and promotion requirements." ECF No. 45-1 at 12. Silverman then proceeds to explain each of these categories of FDCA requirements and Defendants' compliance, rebutting Dr. Sharlin's opinion that Defendants did not comply with the FDCA. ECF No. 45-1 at 12–15. Plaintiffs' argument that Silverman's opinions are not helpful because it does not address Defendants' conduct is unfounded.[5]

Moving to Plaintiffs' argument regarding Silverman's allegedly incomplete document review, "[a]s a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned that opinion rather than its admissibility and should be left for the jury's consideration." *McNees v. Ramirez*,

[5] Defendants also respond that they retained Silverman to rebut Dr. Sharlin, and to that end, he "opines that Dr. Sharlin cannot usurp the FDA's role in establishing standards for complaint reporting, cannot override the FDA's allowance to device manufactures to rely on the independent judgment of medical professionals to determine if a device complaint meets the reporting threshold, and cannot speculate whether Dr. Sharlin's subjective enforcement of the reporting standard would result in the FDA's finding some non-compliance." ECF No. 145 at 6. So, "the exact actions of any given Defendant are not the primary focus or substance of Mr. Silverman's report"—rather, his opinions are concerned with "the Filshie Clip's compliance with the FDA rules and regulations." ECF No. 145 at 6. The Court agrees that even if his testimony does not focus on Defendants' conduct, the above is helpful for the jury in light of Dr. Sharlin's opinions.

No. CV H-17-3815, 2018 WL 8755882, at *2 (S.D. Tex. Dec. 7, 2018) (quoting *Primrose Operating Co. v. Nat'l Am. Ins. Co.*, 382 F.3d 546, 562 (5th Cir. 2004)). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Id.* (quoting *Daubert*, 509 U.S. at 596).

Plaintiffs' arguments regarding Silverman's document review in reaching his opinion go to the bases and sources of his opinion and therefore, impact the weight, not the admissibility of his testimony. *See id.* (arguments that expert looked at only a summary of the medical expenses, did not meet with the plaintiffs directly, and based her opinions on other doctors' reports go to the bases and sources of the expert opinions and therefore affect the weight, not admissibility of her testimony.). If these bases and sources are incorrect or incomplete, then Plaintiffs can effectively address those issues on cross-examination.

For similar reasons, Plaintiffs' unreliable methodology argument—that Silverman did not conduct sufficient investigation into Filshie Clip complaints—goes to the weight, not admissibility of Silverman's testimony. Defendants clarified that they do not intend to offer Silverman's testimony as broadly as Plaintiffs suggest, *i.e.* to show Defendants' compliance for the thirty-year history of the Filshie Clip. Instead, Defendants use Silverman to rebut Dr. Sharlin's opinion that Defendants did not comply with the FDA requirements—Silverman reviewed the same documents that Dr. Sharlin relied upon and came to a different conclusion: that

these documents do not show Defendants' non-compliance with the FDA. Accordingly, Silverman's opinions are based on sufficient facts and data to be admissible. *See Suzlon Wind Energy Corp. v. Shippers Stevedoring Co.*, 662 F. Supp. 2d 623, 667 (S.D. Tex. 2009) ("ABR's argument that Simpkins did not review sufficient facts and data goes to the weight of his opinion, to be brought out in cross-examination and resolved by the jury, not to admissibility") (collecting cases).

IV. CONCLUSION

Therefore, Plaintiffs' motion to limit Mr. Silverman's testimony, ECF No. 130, is **DENIED**.

It is so ORDERED.

Signed on February 26, 2025, at Houston, Texas.

Dena Palermo

Dena Hanovice Palermo
United States Magistrate Judge